

Imaging as a Biomarker: Standards for Change Measurements in Therapy

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:
What can be measured over time?

Day 2: Summary

“The Detailed Measurement Science & Standards Needs –
The What by When and by Whom”
Near, Mid-Term Issues Only

Chair

Jeffrey L. Evelhoch, PhD
Director of Medical Sciences Imaging
Amgen, Inc.

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Breakout Area 3: MRI, MRS, DCE and Diffusion MRI: What can be measured over time?

Measurement Need #1 for Near-Term 1-3 Years

1. *Technology at Issue:* System Phantom
2. *Submitter(s):* Participants of Breakout Area 3
3. *Technological Innovation at Stake:*
 - Lose quantitative MR as a biomarker
 - Lose use of MR in clinical trials
4. *Economic Significance of Innovation:*
 - Pharma – enormous savings in clinical trials
 - Reduction in health care costs
5. *Technical Barriers to the Innovation:*
 - Consensus to defining, characterizing, manufacture, stability the phantom
 - Uniform acquisition protocol
6. *Stage of Innovation Where Barrier Appears:*
 - R&D
 - Market place potential

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI: What can be measured over time?

Measurement Need #1 for Near-Term 1-3 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier:*
 - Measurement of SNR linked to the resolution
 - Resolution
 - MR Geometric (linear & nonlinear) accuracy
 - MR Stability (signal & geometry)
 - Traceability to fundamental quantities
 - Physical stability, construction & temperature dependence of phantom
 - Defining analysis package
8. *Potential Solutions to Measurement Problem:*
 - Use of standard materials
 - Building consensus
 - Software for analysis (web-based?)
 - Well-defined specifications
9. *Potential Providers of Solutions:*
 - NEMA, AAPM, ISMRM, ACR, NIST, phantom manufacturers
10. *What is the role for Government, if Any?:*
 - Material & manufacturing standards (NIST)
 - National & international consensus standards
11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*
 - Contribute to the development
 - Use of standard materials
 - Small contribution needed for government for primary standards & international issues

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI: What can be measured over time?

Measurement Need #1 for Near-Term 1-3 Years

1. *Technology at Issue:* Application Specific Phantoms
2. *Submitter(s):* Participants of Breakout Area 3
3. *Technological Innovation at Stake:*
 - Lose quantitative MR as a biomarker
 - Lose use of MR in clinical trials
4. *Economic Significance of Innovation:*
 - Pharma – enormous savings in clinical trials
 - Reduction in health care costs
5. *Technical Barriers to the Innovation:*
 - Same as system phantom
 - Anatomy, physiology, specific sequence & MR specific properties
 - Often process is dynamic & measures function
 - Analysis software will be more complex
6. *Stage of Innovation Where Barrier Appears:*
 - R&D
 - market place potential

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI: What can be measured over time?

Measurement Need #1 for Near-Term 1-3 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier:*
 - Similar to system phantom
 - Properties relevant to specific applications
 - Properties defined working groups
 - Appropriate approaches & consensus to analysis
8. *Potential Solutions to Measurement Problem:*
 - Same as systems phantom
 - Application specific working groups
 - Prioritization of applications
9. *Potential Providers of Solutions:*
 - PhRMA, NEMA, AAPM, ISMRM, ACR, NIST, NIH, phantom manufacturers
10. *What is the role for Government, if Any?:*
 - Same as system phantom with increased role for NIST
 - NIH Funding
 - FDA for potential health care applications
11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*
 - Contribute to the development
 - Use of standard materials
 - Standards issues will be more complex
 - Cutting edge basic research needed for some applications
 - Significant contribution needed because of the cross industry nature of program impact on US population & regulatory process

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:

What can be measured over time?

Measurement Need #2 for Near-Term 1-3 Years

1. *Technology at Issue:*
2. *Submitter(s):* Participants of Breakout Area 1
3. *Technological Innovation at Stake:*
4. *Economic Significance of Innovation:*
5. *Technical Barrier to the Innovation:*
6. *Stage of Innovation Where Barrier Appears:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:
What can be measured over time?

Measurement Need #2 for Near-Term 1-3 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier.*
8. *Potential Solutions to Measurement Problem:*
9. *Potential Providers of Solutions:*
10. *What is the role for Government, if Any?:*
11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:

What can be measured over time?

Measurement Need #1 for Mid-Term 3-5 Years

1. *Technology at Issue:*
2. *Submitter(s):* Participants of Breakout Area 1
3. *Technological Innovation at Stake:*
4. *Economic Significance of Innovation:*
5. *Technical Barrier to the Innovation:*
6. *Stage of Innovation Where Barrier Appears:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:
What can be measured over time?

Measurement Need #1 for Mid-Term 3-5 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier.*
8. *Potential Solutions to Measurement Problem:*
9. *Potential Providers of Solutions:*
10. *What is the role for Government, if Any?:*
11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:

What can be measured over time?

Measurement Need #2 for Mid-Term 3-5 Years

1. *Technology at Issue:*
2. *Submitter(s):* Participants of Breakout Area 1
3. *Technological Innovation at Stake:*
4. *Economic Significance of Innovation:*
5. *Technical Barrier to the Innovation:*
6. *Stage of Innovation Where Barrier Appears:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:
What can be measured over time?

Measurement Need #2 for Mid-Term 3-5 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier.*
8. *Potential Solutions to Measurement Problem:*
9. *Potential Providers of Solutions:*
10. *What is the role for Government, if Any?:*
11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:
What can be measured over time?

Measurement Need #3 for Mid-Term 3-5 Years

1. *Technology at Issue:*
2. *Submitter(s):* Participants of Breakout Area 1
3. *Technological Innovation at Stake:*
4. *Economic Significance of Innovation:*
5. *Technical Barrier to the Innovation:*
6. *Stage of Innovation Where Barrier Appears:*

Breakout Area 3: MRI, MRS, DCE and Diffusion MRI:
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Measurement Need #3 for Mid-Term 3-5 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier.*
8. *Potential Solutions to Measurement Problem:*
9. *Potential Providers of Solutions:*
10. *What is the role for Government, if Any?:*
11. *If There is a Government Role, Why Industry Says It Can't/Won't Pay for That Part of Solution:*